

Notice of Allowability

Application No.

09/554,860

Examiner

Nora M. Rooney

Applicant(s)

BRUCK ET AL.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 09/19/2007.
2. ☒ The allowed claim(s) is/are 1 and 18-20.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date See Continuation Sheet
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 09/19/2007 & 09/20/2007.

EXAMINER'S AMENDMENT

1. Applicant's amendment filed on 09/19/2007 is acknowledged.

Claims 1, 12 and 18-20 are pending.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R.

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

3. Authorization for this amendment was given in a telephone interview with Jason Fedon on 10/01/2007.

4. Applicant's IDS documents filed on 09/19/2007 and 09/20/2007 are acknowledged.

The application has been amended as follows:

In the Claims:

5. Please replace Claim 1 with --A recombinant mutant pro-DerP1 allergen of the DerP1 pre-pro-protein of SEQ ID NO:1 wherein SEQ ID NO:1 comprises a cysteine to alanine substitution at amino acid position 132 and wherein said pro-DerP1 allergen is from *Dermatophagoides pteronyssinus*--.

6. Please replace Claim 18 with --A therapeutic formulation comprising the recombinant mutant pro-DerP1 allergen as claimed in claim 1 and an adjuvant.--.

7. Please replace Claim 19 with --The therapeutic formulation as claimed in claim 18, wherein the adjuvant is a preferential stimulator of the Th1-type immune response.--.

8. Please replace Claim 20 with --The therapeutic formulation as claimed in claim 18, wherein the adjuvant comprises at least one selected from the group consisting of QS21 and 3-O-deacylated monophosphoryl lipid A.--.

9. Claim 12 is cancelled.

10. Claims 1 and 18-20 are allowed in light of Creighton et al. (PT0-892, Reference U) which teaches that secreted proteolytic enzymes are made as prezymogens (pre-pro-proteins). The signal peptides of pre-zymogens (pre-pro-proteins) are cleaved before storage of the enzymes as inactive zymogens (pro-proteins). Hence, pro-proteins are pre-pro-proteins without their signal peptide. Therefore, the pro-DerP1 allergen would have been known by those skilled in the art to have been the pre-pro-DerP1 allergen of SEQ ID NO:1 minus the 18 amino acid signal peptide.

11. Claims 1 and 18-20 are allowed.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 30, 2007

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

Maheer M. Haddad
MAHER M. HADDAD
PRIMARY EXAMINER